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EXAMINER	
SPIEGLER, ALEXANDER H	
ART UNIT	**PAPER NUMBER**
1637	25

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,363	GABERT, JEAN	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21,24-27,29-32 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21,24-27,29-32 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to Paper No. 24, filed on July 3rd, 2003. Currently, claims 17-21, 24-27, 29-32 and 36-42 are pending and are rejected.

2. This action contains new rejections, and therefore, this action is made NON-FINAL.

Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-21, 24-27, 29-32, 36-39 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have not provided any support (e.g., by describing specific page and line numbers) for the amendments made to the claims (for example, see independent claims 32 and 39). In Claim 39, Applicant's have amended the claims to recite, "indiscriminately amplifying all of the DNA or cDNA of said fusion genes". The use of the recitation of "indiscriminately amplifying all" of the DNA or cDNA is not supported by the specification. Additionally, for example, the kit of claims 32-38 is drawn to a kit comprising one primer, which binds to a target gene to form a complex, "which provides indiscriminate amplification". This recitation is also not found in the specification, nor is there support for any "complex which provides

indiscriminate amplification" Accordingly, Applicants should specifically address where support exists (by page and line number) for the newly amended claim limitations.

Additionally, Claim 21 is drawn to a set of primers, wherein one primer "consists of a sequence containing a cassette of 40 to 60 nucleotide and 10 to 20 T nucleotides, and the second primer is a random repeat of nucleotides". In Applicants response on page 8, Applicants assert there is support for this claim on page 7, lines 25-28.

Page 7, lines 25-28 states, "Suitable sequences include a cassette with about 40 to 60 nucleotides with 10 to 20 T nucleotides on one end, *or alternatively*, a random repeated nucleotide pattern". Thus, this passage supports the alternative use of either the sequence including the cassette with about 40 to 60 nucleotides with 10 to 20 T nucleotides on one end, **or**, a random repeated nucleotide pattern. Claim 21 is drawn to using both sequences in one reaction, whereas, the specification only supports using either one or the other, and not both.

Response to Applicants Arguments

Applicants argue support for Claim 39 is located on several pages including pages 3-7, 10 and 12, for example (Applicants response page 8). However, none of these pages contain or support, the phrases "indiscriminately", "indiscriminately amplifying all of the DNA or cDNA of said fusion genes" or a kit comprising one primer, which binds to a target gene to form a complex, "which provides indiscriminate amplification".

Specification

5. The disclosure is objected to because of the following informalities:

A) Applicants could amend the specification to include the heading "Detailed Description of the Invention".

B) Claim 36, recites, "streptavidine", which should be amended to recite, "streptavidin".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-21, 24-27, 29-32 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 17-21, 24-27, 29-31 and 39-42 over "a patient cDNA" because a patient does not contain cDNA; cDNA would be made from a patient's RNA.

B) Claims 17-21, 24-27, 29-31 and 39-42 over "indiscriminately" because it is not clear as to how "all of the DNA or cDNA" can be "indiscriminately" amplified when the method requires a specific primer complementary to the target gene. That is, the specific primer would necessarily amplify a specific target gene, and therefore, this part of the amplification cannot be considered as "indiscriminate".

C) Claims 17-21, 24-27, 29-31 and 39-42 are indefinite over "one of the primers being complementary to the nucleotide sequence of the target gene" because "the nucleotide sequence" lacks antecedent basis. Additionally, it is not clear as to what sequence is this primer complementary to, is this primer specific to a particular region, or is this a random primer? For example, can the primer that is complementary to the nucleotide sequence of the target gene have one region that is complementary to the target and another region that is an arbitrary or non-specific.

D) Claim 21 because it is not clear as to which primer is considered to be an anchored primer and which is considered to be specific for the target gene. Claim 21 refers to one primer that has 10 to 20 T nucleotides (of which Applicants allege is understood to be a poly T tail, see Applicants response on page 9), and which could act as an anchored primer, and another primer that is a random repeat of nucleotides. Claim 39 refers to one primer that is specific for the target gene and another primer that is an anchored primer. Thus, it is not clear in Claim 21, which primers correspond with the primers of Claim 39. Furthermore, it is not clear as to what is encompassed by "random repeat of nucleotides". Can this be a series of repeats such as "CACACACACACA" or "NNNNNNNNNNN", or some other "random repeat of nucleotides".

E) Claim 25 because the claims should set forth active method steps, such as "reverse transcribing" and "amplifying", rather than "the RT synthesis" and "a PCR amplification". Furthermore, the "RT step" should refer to a specific, active method step.

F) Claim 26 "over as a nested amplification cycle" because it is not clear as to what this limitation adds to the claim. Furthermore, it is not clear as to what it is meant by "using an internal sense primer with respect to the first primer, where the 3' primer us the same on each cycle" because it is not clear as to how one "uses" one primer "with respect" to another primer. It is suggested that Applicants re-write Claims 25 and 26 in independent form to clearly recite each step sequentially.

G) Claims 32 and 36-38 are indefinite over "complex which provides indiscriminate amplification" because it is not clear as to what primer binding to a target gene "provides indiscriminate amplification". That is, how can the "complex" provide "indiscriminate

amplification", since the complex refers to a product, whereas "indiscriminate amplification" refers to a process.

H) Claims 40-42 over "the hybridized products", "the enzyme substrate" and "the probe/PCR product reactive mixture" because these recitations lack antecedent basis. Furthermore, it is not clear as to what is meant by "marked" antibodies. This recitation is not defined, nor an art recognized term. Does this refer to an anti-digoxygenine antibody?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 17-18, 20 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS).

Regarding Claims 39, Ratech teaches an in vitro diagnostic method for detecting and identifying DNA sequences of fusion genes comprising a target gene and a fusion partner, said fusion genes being involved in cancer associated with rearrangements of the target gene wherein a patient nucleic acid is subjected to an anchored PCR comprising;

a) "indiscriminately" amplifying all of the DNA or cDNA of said by PCR, with one pair of primers, one of the primers being complementary to the nucleotide sequence of the target gene, the other primer being an anchored primer, wherein all the DNA or cDNA sequences of the

target gene are amplified (see pages 527-528, Fig. 1 and Table 1) (teaching the use of a target specific primer and an anchored primer comprising a stretch of dTs, see, for example, page 528, column 2, paragraph 3; Fig. 1 and Table 1),

b) obtaining PCR products (see Fig. 1, page 528, column 2),

c) hybridizing the PCR products with probes specific for said fusion partner (see page 528; 530, second column, last sentence; and Figs. 1-2)

d) detecting the presence of rearrangements of the target gene, and, identifying the fusion genes of any detected rearrangements (See pages 528-530 and Figs. 1-2).

Regarding Claim 17, Ratech teaches the primers consist of 25 to 40 nucleotides, including one primer, which comprises 17 T nucleotides (See Table 1, for example).

Regarding Claims 18 and 20, Ratech teaches labeling said PCR products (e.g., by ethidium bromide), denaturing said labeled PCR products, and contacting the denatured labeled PCR products with a labeled nucleotide sequences complementary to a fusion partner nucleotide sequence (see page 528, second column to page 529, first column; Fig. 1 and page 530, second column, last sentence). Ratech also teaches nested PCR (see page 528, for example).

10. Claims 32 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Morris et al. (USPN 5,770,421).

The claims are drawn to a kit "for identifying DNA sequences of fusion genes", said kit comprising a pair of primers, wherein one of the primers is complementary to the nucleotide sequence of a target gene and binds to said target gene to form a complex which provides "indiscriminate amplification", and the other primer is an "anchored primer", and at least one probe specific for a fusion partner, said at least one probe being bound to a support.

It is noted that the specification does not define an "anchored primer", and therefore, a primer capable of hybridizing to another nucleic acid (e.g., a template) is considered to be "anchored primer".

Regarding Claim 32, Morris teaches methods of detecting the NPM/ALK fusion gene, including PCR and nucleic acid hybridization (see cols. 2-3, for example). Morris teaches the use of two primers, (one of the primers is complementary to the nucleotide sequence of a target gene and binds to said target gene to form a complex which provides "indiscriminate amplification", and the other primer is an "anchored primer") (col. 21-23, for example). Morris also teaches probes specific for fusion genes (col. 17-20, for example), which can be immobilized on solid supports (col. 20, ln. 42-49, for example). Morris also teaches the probe may be labeled with an affinity label, such as biotin (col. 12, ln. 45-49, for example).

Regarding Claim 37, Morris teaches the probes may be immobilized on beads (col. 20, ln. 42-49). It is noted that the claims are drawn to a "miniaturized" support, however, the specification does not define a "miniaturized" support, and therefore, a bead is considered to be a "miniaturized" support.

Finally, Regarding Claims 32 and 37, Morris teaches the above reagents can be packaged in a kit (cols. 4, ln. 9-12 and col. 12).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS) as applied to claims 17-18, 20 and 39 above, and further in view of Fodor et al. (USPN 6,309,822).

The teachings of Ratech are presented above and are incorporated herein. Specifically, Ratech teaches a method of detecting and identifying DNA sequences of fusion genes comprising a target gene and a fusion partner, said fusion genes being involved in cancer associated with rearrangements of the target gene wherein a patient nucleic acid is subjected to an anchored PCR, wherein the detection is carried out using probes specific for said fusion partner. Ratech does not teach that the probes are covalently bonded on a support.

However, Fodor teaches DNA chips comprising nucleic acid probes covalently bound to said DNA chips for use in detection purposes (see cols. 2-10, for example). Specifically, teaches the advantages of using oligonucleotide probe arrays include, "1) Efficiency of production; 2) Reduced intra- and inter-array variability; 3) Increased information content; and 4) Higher signal to noise ration (improved sensitivity)" (col. 12, ln. 53-58).

Accordingly, in view of the teachings of Fodor, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ratech so as to have included the step of detecting fusion partners using nucleic acid probes covalently bonded on a support, in order to have achieved the benefits stated by Fodor of providing a more efficient and sensitive detection assay.

14. Claims 24-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS) as applied to claims 17-18, 20 and 39 above, and further in view of Felix et al. (USPN 6,368,791).

The teachings of Ratech are presented above and are incorporated herein. Specifically, Ratech teaches an in vitro diagnostic method for detecting and identifying DNA sequences of fusion genes comprising a target gene and a fusion partner, said fusion genes being involved in cancer associated with rearrangements of the target gene wherein a patient nucleic acid is subjected to an anchored PCR. Ratech teaches does not teach the method wherein the target gene is MLL.

However, Felix et al. teaches translocations in the MLL gene at chromosome band 11q23 "is associated with most cases of ALL which occur during infancy and with most monoblastic variants of AML which occur during the first four years of life" (col. 1, lines 46-51). That is, rearrangements of MLL are known to be associated with acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML) is children. Feliz also teaches that PCR can be used for identifying MLL gene rearrangements (see cols. 3-8, 13-16, 21-22 and Examples 1-7). Specifically, Felix teaches the use of Exon 5 specific primers in PCR, as well as, nested PCR comprising internal sense primers (see cols. 15-16, 21 and 22, for example).

Accordingly, in view of the teachings of Felix, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ratech so as to have detected rearrangements in the MLL gene, in order to have achieved the benefit of detecting ALL and AML in young children.

15. Claims 27 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS), in view of Felix et al. (USPN 6,368,791), as applied to claims 24-26 and 29 above, further in view of Hoeltke et al. (Cellular and Molecular Biology (1995) 41(7): 883-905, previously cited)

The teachings of Ratech and Felix are presented above and are incorporated herein. Specifically, the references teach an in vitro diagnostic method for detecting and identifying DNA sequences of fusion genes comprising an MLL gene and a fusion partner, said fusion genes being involved in cancer associated with rearrangements of the target gene wherein a patient nucleic acid is subjected to an anchored PCR. The references teach contacting a probe specific for MLL with denatured PCR products, but do not teach that the PCR products have been denatured and labeled with digoxygenine, and carrying out the detection using the digoxygenine system as outline in steps f) – g) of Claim 28.

However, Hoeltke teaches labeling a PCR product with digoxygenine, in order to hybridize a probe with the PCR product where complementary bases are present, and providing hybridization products, contacting the hybridization products, when obtained, with anti-digoxygenine antibodies coupled to an enzyme and capable of reacting with a substrate of said enzyme to release by a detectable product, said contacting thereby producing a probe/PCR

product reactive complex and contacting the probe/PCR product reactive complex with the substrate, and detecting the detectable product so formed, if any (pgs. 884, column 1; pgs. 886 to 887, 1st column; pgs. 889-890, 897 and 889). Hoeltke teaches the digoxygenine labeling and detection system is advantageous for its evaluated and proven increased sensitivity and specificity.

Accordingly, in view of the teachings of Hoeltke, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Ratech and Felix so as to have included the steps of using the digoxygenine labeling and detection system, in order to have achieved the benefits of providing a more sensitive and specific detection assay.

16. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS) as applied to claims 17-18, 20 and 39 above, and further in view of Denny, C.T. (Cancer Investigation (1996) 14(1): 83-88).

The teachings of Ratech are presented above and are incorporated herein. Specifically, Ratech teaches an in vitro diagnostic method for detecting and identifying DNA sequences of fusion genes comprising a target gene and a fusion partner, said fusion genes being involved in cancer associated with rearrangements of the target gene wherein a patient nucleic acid is subjected to an anchored PCR. Ratech teaches does not teach the method for detecting rearrangements in fusion genes involved in solid tumors, such as Ewing tumor.

However, Denny teaches that the Ewing's sarcoma has been "linked to a specific chromosomal abnormality involving a reciprocal translocation between chromosomes 11 and 22: t(11;22)(q24;q12)"; detectable in approximately 86% of tumors, and on a molecular level at a

frequency of almost 90% (see pg. 84, 1st column). Therefore, Denny teaches the importance of detecting rearrangements in genes associated with Ewing's sarcoma (tumor).

Accordingly, in view of the teachings of Denny, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ratech so as to have detecting rearrangements in genes involved in Ewing's sarcoma, in order to have achieved the benefit of providing an effective means of detecting Ewing's sarcoma in over 85% of tumors, thus improving detection of Ewing's sarcoma, and aiding in future studies for inhibiting tumor growth.

17. Claims 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (USPN 5,770,421), as applied to claims 32 and 37 above, and in view of Smith et al. (USPN 5,753,439).

The teachings of Morris are presented above and are incorporated herein. Specifically, Morris teaches a kit comprising two primers of the claimed kit and a probe immobilized to a solid support. Morris also teaches that the probe can be labeled with an affinity label, such as biotin. Morris does not teach the probe bound to a solid support through a biotin group bonded to streptavidin coupled to said support or the use of a DNA chip as a solid support.

However, Smith teaches the rapid detection of nucleic acids using an array of probes (see abstract and col. 2, for example). Specifically, Smith teaches the use of DNA chips and other supports (col. 7, ln. 30-42), wherein nucleic acid probes labeled with biotin are attached to the solid support through streptavidin (see col. 12, ln. 43-45).

Accordingly, in view of the teachings of Smith, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the kit of Morris to

have included the probe bound to a solid support through a biotin group bonded to streptavidin coupled to said support, wherein said support could be a DNA chip, in order to have achieved the benefit of providing a more efficient means of detecting a target nucleic acid.

18. Claims 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rassenti et al. (Annals of the NY Academy of Sciences (1995) 764: 463-473), in view of the Stratagene Catalog (1988).

Regarding Claims 32 and 37 Rassenti teaches a pair of primers, wherein one of the primers is complementary to the nucleotide sequence of a target gene and binds to said target gene to form a complex which provides "indiscriminate amplification", and the other primer is an anchored primer, and at least one probe specific for a fusion partner, said at least one probe being bound to a "miniaturized" support (see pages 464-465 (teaching the target specific primer and anchored primer) and pages 466-467 (teaching at least one probe specific for said fusion partner, said probe being bound to a support).

Rassenti does not teach packaging the above reagents in a kit.

However, reagent kits for performing DNA assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the above reagents in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art.

19. Claims 32, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratech et al. (Am. J. of Clin. Path. (1993) 100:527-533, cited in the IDS), in view of Fodor et al. (USPN 6,309,822), as applied to Claim 19 above, and in further view of the Stratagene Catalog (1988).

The teachings of Ratech and Fodor are presented above and are incorporated herein. Specifically, the references teach a method of detecting and identifying DNA sequences of fusion genes comprising a target gene and a fusion partner, using a pair of primers, wherein one of said primers is complementary to the nucleotide sequence of a target gene and binds to said target gene to form a complex which provides "indiscriminate amplification", and the other primer is an anchored primer, and at least one probe specific for a fusion partner, said at least one probe being bound to a DNA chip.

Ratech and Fodor do not teach packaging the above reagents in a kit.

However, reagent kits for performing DNA assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the above reagents in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art.

Conclusion

20. No Claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
October 15, 2003

CARLA J. MYERS
PRIMARY EXAMINER